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EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
1644	3

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/025,567	NASH ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-23 are pending and are being acted upon in this Office Action.

2. The disclosure is objected to because of the following informality: Cross-reference to related application should have been on the first line of the first page of the specification and not at the title page. Appropriate action is required.

3. Claim 16 is objected to because "CSantigen" should have been "CS antigen".

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 1-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling only for (1) a microbial adherence inhibitor for administration to food animals to prevent the adherence of targeted colony-forming immunogens in the rumen or intestinal tracts of said food animal wherein the colony-forming immunogens are selected from the group consisting of *P. anaerobius, C. sticklandii, C. aminophilium, E. Coli, Listeria, Salmonella* and *Campylobacter* produced by the method inoculating female birds, in or about to reach their egg laying age, with said colony-forming immunogens; allowing a period of time sufficient to permit the production in the bird of antibody to said targeted immunogen; Harvesting the eggs laid by the birds; Separating the antibody-containing contents of said eggs from the shells and Drying said separated antibody-containing contents of said eggs, **does not** reasonably provide enablement for *any* microbial adherence inhibitor for administration to food animals to prevent the adherence of *any* "targeted colony-forming immunogens", in the rumen or intestinal tracts of said food animal produced by the method inoculating female birds, in or about to reach their egg laying age, with (1) *any* "colony-forming immunogens", (2) *any* "colony-forming immunogens are known to cause food borne illness in humans", or (3) *any* "particular targeted immunogen" as set forth in claims 1-12 and 22-23 for promoting the growth of food animals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in **scope** with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation.

The specification discloses only five adherence inhibitors wherein the inhibitors are egg antibodies that binds specifically to *P. anaerobius*, *C. Sticklandii*, *C. aminophilum*, *E coli serogroup 0157*, produced by the method of inoculating female bird with the specific immunogen such as *P. anaerobius*, *C. Sticklandii*, *C. aminophilum*, and *E coli* serogroup *0157,* harvesting the eggs, mixing and pasteurizing the whole egg prior to mixing with the animal feed or water with said egg antibody to prevent the adherence of said specific immunogen in the intestinal tracts of the animal and thereby promote the growth of the animals.

The specification does not teach how to make much less how to use any microbial adherence inhibitor other than the ones mentioned above because the terms "colony-forming immunogens", "P antigen", "CS antigen", "CA antigen", "Listeria antigen", "Salmonella antigen" and "Campylobacter antigen" without the specific amino acid sequence (SEQ ID NO) have no structure.

Stryer *et al* teach that a protein is highly dependent on the overall structure of the protein itself and that the primary amino acid sequence determines the conformational of the protein (See enclosed appropriate pages).

Further, given the indefinite number of undisclosed immunogens or antigens such as any "P antigen", "CS antigen", "CA antigen", "Listeria antigen", "Salmonella antigen" and "Campylobacter antigen", there is insufficient working examples demonstrating that microbial adherence inhibitor such as any avian antibody produced by inoculating the birds with any undisclosed antigen is effective for inhibiting the ability of any organism to adhere to the rumen of or intestinal tracts of animals to reduce the ability of bacteria such as *P. anaerobius*, *C. Sticklandii*, *C. aminophilum*, *E coli* serogroup 0157: H7, *Salmonella,* and *Campylobacter* to multiply. It is well known that not all immunogen or antigen on any given microorganism plays a role in adherence and colonizing the rumen or intestinal tract of any animal. Even if the

immunogen is known, the antibody generated from the specific immunogen can only be specific to that immunized immunogen. For example, immunizing an egg-laying hen with bacteria *P anaerobius* can generate antibody only specific to said bacteria and under no circumstance can the hen generate antibody to the other bacteria such as E coli.

Kuby *et al* teach that antibody epitopes (B cell epitopes) are not linear and are comprised of complex three-dimensional array of scattered residues which will fold into specific conformation that contribute to binding (See Kuby 1994, page 94, in particular). Immunization with a peptide fragment derived from a full-length polypeptide may result in **antibody specificity** that differs from the antibody specificity directed against the native full-length polypeptide.

Abaza *et al* teach that even a single amino acid substitution outside the antigenic site can exert drastic effects on the reactivity of a protein with monoclonal antibody against the site (See abstract, in particular). Since the amino acid sequence of the antigen such as "P antigen", "CS antigen", "CA antigen", "Listeria antigen", "Salmonella antigen" and "Campylobacter antigen" is unknown, it follows that the antibody generated from any immunogen is not specific, in turn; the antibody that binds specifically to said undisclosed antigen as a microbial adherence inhibitor for inhibiting the adherence of bacteria in the rumen of food animal is not enabled. Given the indefinite number of undisclosed antigen and immunogen, it is unpredictable which microbial adherence inhibitor produced by immunizing a hen with any undisclosed antigen or immunogen will have the same antibody specificity as the antibody that binds specifically to protein-wasting immunogen such as *P. anaerobius*, *C. sticklandii*, *C. aminophilium*, E coli, Listeria, Salmonella and Campylobacter in turn, would be useful for any purpose.

For these reasons, it would require undue experimentation of one skilled in the art to practice the claimed invention. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

In re wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the decision of the court indicates that the more unpredictable the area is, the more specific enablement is necessary. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take an undue amount of experimentation for one skilled in the art to practice the claimed invention.

6. Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of *any* microbial adherence inhibitor for administration to food animals to prevent the adherence of *any* "targeted colony-forming immunogens", in the rumen or intestinal tracts of said food animal produced by the method inoculating female birds, in or about to reach their egg laying age, with (1) *any* "colony-forming immunogens", (2) *any* "colony-forming immunogens are known to cause food borne illness in humans", or (3) *any* "particular targeted immunogen" as set forth in claims 1-12 and 22-23 for promoting the growth of food animals.

The specification discloses only five adherence inhibitors wherein the inhibitors are egg antibodies that binds specifically to *P. anaerobius*, *C. Sticklandii*, *C. aminophilum*, *E coli serogroup 0157*, produced by the method of inoculating female bird with the specific immunogen such as *P. anaerobius*, *C. Sticklandii*, *C. aminophilum*, and *E coli* serogroup *0157,* harvesting the eggs, mixing and pasteurizing the whole egg prior to mixing with the animal feed or water with said egg antibody to prevent the adherence of said specific immunogen in the intestinal tracts of the animal and thereby promote the growth of the animals.

Other the specific organisms as immunogen mentioned above for a method of for the production of a microbial adherence inhibitor for administration to food animals to substantially prevent the adherence of colony-forming organisms, there is inadequate written description about the structure associated with function of (1) *any* "colony-forming immunogens", *any* "P antigen" from *P. anaerobius*, *any* "CS antigen" from *C. sticklandii*, *any* "CA antigen" from C. aminophilium, *any E coli*, *any* "Listeria antigen" from Listeria, *any* "Salmonella antigen" from *Salmonella*, or *any* "Campylobacter antigen" from Campylobacter because the term immunogen and antigen do not convey a specific structure without the specific amino acid sequence or SEQ ID NO. Further, inoculating any female bird with the specific organisms can only produce microbial inhibitor such as avian antibody to said organisms. Given the indefinite number of undisclosed "colony-forming immunogens" and "antigen" even from any one specific organism mentioned above, the microbial adherence inhibitor produced by inoculating with any undisclosed antigen is not adequately described.

Since the specification discloses only a microbioal inhibitor produced by inoculating with six colony-forming immunogens such as bacteria selected from the group consisting of *P. anaerobius*, *C. Sticklandii*, *C. aminophilum*, *E coli* serogroup 0157: H7, *Salmonella,* and *Campylobacter*, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.*

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 1-7 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The "particular targeted protein-wasting immunogen" in claims 1 and 22 is ambiguous and indefinite because it is not clear which particular targeted protein-wasting immunogen to be used for inoculating the bird. One of ordinary skill in the art cannot appraise the metes and bounds of the claimed invention. Further, the term "substantially" in claims 1 and 22 is not defined in the specification.

The limitation "said colony-forming immunogen" in claims 2-5 has no antecedent basis in base claim 1. Base claim 1 recites "colony-forming immunogens".

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-2, 4-5, 8-9, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat No. 5,080,895 (Jan 1992; PTO 1449).

The '895 patent teaches a yolk antibody that binds specifically to E coli and the reference antibody inherently inhibits the microbacteria from adhering to the intestinal track of livestock since the reference antibody is able to prevent diarrhea that results in dietary protein wasting. The reference microbial adherence inhibitor is produced by the method of inoculating an egg laying female birds such as the hen in their egg laying age with an immunogen such as bacterium E coli, wherein the reference E coli is a colony-forming bacteria (See column 5, lines 29-30, in particular), allowing a period of time such as a few weeks after inoculation sufficient to permit the production of bird antibody that binds to the targeted immunogen such as E Coli (See column 5, lines 47-60, column 6, 10-18, in particular). The reference method includes collecting the egg laid by the hen (See column 6, line 1, in particular), separating the antibody against the inoculated immunogen from the yolk or albumin or both (See column 6, lines 19-20, in particular), drying the separated egg antibody from the shells and drying the separated the reference antibody by spray drying or lyophilizing to form powder product (See column 6, line 24-25, in particular). The reference microbial adherence inhibitor such as dried egg antibody is used as an additive to food for animal or as a solution such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the animal (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging column 6, lines 1-49, column 9, lines 43-57, column 10, line 29-31, in particular). The '895 patent further teaches various microbial adherence inhibitors such as egg antibodies produced by the method of inoculating the female bird with immunogens such as K88, K99 and 987P from E coli of interest and egg antibody is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27). Thus, the reference teachings anticipate the claimed invention.

11. Claims 1-2, 4-5, 8-9, and 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat No 4,748,018 (May 31, 1988; PTO 1449) or Sugita-Konishi *et al* (Biosci Biotechnol Biochem 60(5): 886-8, May 1996; PTO 892) or Yokoyama *et al* (Vaccine 16(4): 388-93, Feb 1998; PTO 892).

The '018 patent teaches IgY antibody that binds specifically to colony forming immunogen or combination of immunogen (antigen) such as *E coli, Listeria, Salmonella* and *Campylobacter* (See column 5, lines 1-30, column 6, line 22-25, in particular). The reference

antibody is inherently is a microbial adherence inhibitor that is produced by the method of inoculating an egg laying female birds such as the hen in their egg laying age with the reference immunogen or immunogens such as bacterium as E coli, Listeria, Salmonella and Campylobacter, wherein the reference immunogens are colony-forming bacteria that are known to cause food borne illness in humans by decreasing an animal's ability to absorb nutrient, allowing a period of time sufficient to permit the production of bird antibody that binds to the targeted immunogens, collecting the egg laid by the hen, purifying the reference antibody and lyophilizing or drying the separated egg antibody (See column 9, lines 17 bridging column 10, lines 1-29, in particular). The '018 patent teaches that the avian antibody produced by domesticated fowl which has been immunized against any antigen or antigens is useful for a method of passive immunity (See abstract, in particular). A product is a product, irrespective of its intended use.

Sugita-Konishi *et al* teach a microbial adherence inhibitor such as IgY antiobody obtained from hens immunized with a mixture of bacteria such as *Salamonella* that is responsible for samonella enteritidis, the reference microbial adherence inhibitor inhibits the adhesion of *Salamonella* to human intestinal cells (Caco 2) in culture (See abstract, and Materials and Methods, in particular). A product is a product, irrespective of its intended use.

Yokoyama *et al* teach a microbial adherence inhibitor such as chicken egg holk homotypic antibodies specifc for an colony-forming immunogen such as the outer membrane proteins (OMP) of Salmonella. The reference microbial adherence inhibitor inhibits the adhesion of *Salamonella* to Hella cells and is useful as oral passive vaccine against Salmonellosis caused by Salmonella enteritidis and S. typhimurium (See abstract, (See abstract, and Materials and Methods, in particular). A product is a product, irrespective of its intended use or how it is made. Thus, the reference teachings anticipate the claimed invention.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1-3, 8-10, 13, 16, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (Jan 1992; PTO 1449), US Pat No. 4,747,018 (May 1988; PTO 1449), Sugita-Konishi *et al* (Biosci Biotechnol Biochem 60(5): 886-8, May 1996; PTO 892) or Yokoyama *et al* (Vaccine 16(4): 388-93, Feb 1998; PTO 892) each in view of Krause *et al* (Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892).

The teachings of the '895 patent, the '018 patent, Sugita-Konishi *et al* and Yokoyama *et al* have been discussed supra.

The claimed invention in claim 3 differs from the teachings of the references only that the microbial adherence inhibitor wherein the colony-forming immunogen is from the class consisting of *P. anaerobius*, *C. sticklandii*, and *C. aminophilium*.

The claimed invention in claim 10 differs from the teachings of the references only that the microbial adherence inhibitor wherein the colony-forming immunogens are from the class consisting of *P. anaerobius*, *C. sticklandii*, and *C. aminophilium*.

The claimed invention in claim 13 differs from the teachings of the references only that the microbial adherence inhibitor wherein the protein-wasting immunogen is P antigen from *P. anaerobius*.

The claimed invention in claim 16 differs from the teachings of the references only that the microbial adherence inhibitor wherein the protein-wasting immunogen is CS antigen from *C. sticklandii*.

The claimed invention in claim 19 differs from the teachings of the references only that the microbial adherence inhibitor wherein the protein-wasting immunogen is CA antigen from *C. aminophilium*.

Krause *et al* teach *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* are responsible for nutrition depletion and the growth of livestock (See entire document). Krause *et al* further teach adding antibiotic such as monensin as a ruminant feed additive decreases the number of *P. anaerobius* and *C. sticklandii* but not the number of *C. aminophilium* in livestock.

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to substitute the immunogen such as the E coli as taught by the '895 patent, or the *E coli, Listeria, Salmonella* and *Campylobacter* as taught by the '018 patent or the *Salamonella* as taught by Sugita-Konishi *et al* or the (OMP) of Salmonella as taught by Yokoyama *et al* for the colony forming immunogen or antigen such as *Peptostreptococcus*

anaerobius, Closteridium sticklandii, and/or Clostridium aminophilium as taught by Krause *et al* for a microbial adherence inhibitor such as egg antibody that binds specifically to said antigens produced by the egg laying hens a taught by the '892 patent, the '018 patent, Sugita-Konishi *et al,* Yokoyama *et al* and Krause *et al.* From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because Krause *et al* teach *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* are responsible for nutrition depletion and the growth of livestock by adhering to the rumen of food animals (See entire document). The '895 patent teaches the method of making bird antibody to any bacterial of interest and bird antibody is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27) and the bird antibody against the immunogen of interest as a food additive is effective for a method of preventing the immunogen from adhering to the rumen or intestinal tracts of livestock (food animal), which inherently promotes the growth of livestock by decreasing diarrhea such as waste of dietary protein caused by the presence of protein-wasting immunogen (See abstract, and claims of '895, in particular). The '018 patent teaches that the avian antibody produced by domesticated fowl which has been immunized against any antigen or antigens is useful for a method of passive immunity (See abstract, in particular). Sugita-Konishi *et al* teach that IgY antibody obtained from hens immunized with a mixture of bacteria such as *Salamonella* that is responsible for samonella enteritidis is useful as a microbial adherence inhibitor that inhibits the adhesion of *Salamonella* to human intestinal cells (Caco 2) (See abstract, and Materials and Methods, in particular). Yokoyama *et al* teach that chicken egg yolk homotypic antibodies specifc for an colony-forming immunogen such as the outer membrane proteins (OMP) of Salmonella is useful as a microbial adherence inhibitor that inhibits the adhesion of *Salamonella* as an oral passive vaccine against Salmonellosis caused by Salmonella enteritidis and S. typhimurium (See abstract, (See abstract, and Materials and Methods, in particular).

14. Claims 1 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (Jan 1992; PTO 1449), US Pat No. 4,747,018 (May 1988; PTO 1449), Sugita-Konishi *et al* (Biosci Biotechnol Biochem 60(5): 886-8, May 1996; PTO 892) or Yokoyama *et al* (Vaccine 16(4): 388-93, Feb 1998; PTO 892) each in view of US Pat 6,086,878 (Jul 2000, PTO 892) and US Pat No. 4,166,867 (Sept 1979, PTO 892).

The teachings of the '895 patent, the '018 patent, Sugita-Konishi *et al,* and Yokoyama *et al* have been discussed supra.

The claimed invention in claim 6 differs from the references only that the microbial adherence inhibitor wherein the drying of the separated antibody-containing contents of said eggs is achieved by coating dry feed carrier material with the antibody-containing contents of said eggs.

The claimed invention in claim 7 differs from the references only that the microbial adherence inhibitor wherein the dry feed carrier material form a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat the directly onto food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46); the reference dried egg powder can be used in drinks, protein supplement (See column 9, lines 47-8, in particular). The '878 patent further teaches there is no need to separate the yolk form the albumin, except to achieve higher concentration of antibody (See column 9, line 62-65, in particular).

The '867 patent teaches a method of making a high performance palatable horse feed comprising soybean hulls, rice hulls cottonseed hulls which provide the fibrous material and cereal grain such as corn and distilled dried grains provide the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to coat any of the animal feed such as soybean hulls, rice hulls cottonseed hulls, cereal grain such as corn and distilled dried grains as taught by the '867 patent with the

microbial adherence inhibitor such as the IgY antibody that binds specifically to either *E coli, Listeria, Salmonella* or *Campylobacter* as taught by the '895 patent, the '018 patent, Sugita-Konishi *et al,* or Yokoyama *et al* that has been spray-dried as taught by the '878 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the '867 patent teaches the carrier material such as soybean hulls, rice hulls and cottonseed hulls provide the fibrous material and provide adequate structural strength or integrity to the final feed pellets to effect stool normality (See column 3, lines 14-16, in particular). The '878 patent teaches hyperimmunized spray-dried egg powder is useful for mixing with any animal feed or sprayed directly to coat the food pellets to maintaining antibody titers (See column 9, lines 37-46). The '895 patent teaches that adding bird antibody (IgY) against any desired immunogen of interest as a feed additive can promote the growth of food animals by preventing diarrhea in livestock since the method of making bird antibody to any immunogen (bacteria) of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27). The '018 patent teaches that the avian antibody produced by domesticated fowl which has been immunized against any antigen or antigens is useful for a method of passive immunity (See abstract, in particular). Sugita-Konishi *et al* teach that IgY antibody obtained from hens immunized with a mixture of bacteria such as *Salamonella* that is responsible for samonella enteritidis is useful as a microbial adherence inhibitor that inhibits the adhesion of *Salamonella* to human intestinal cells (Caco 2) (See abstract, and Materials and Methods, in particular). Yokoyama *et al* teach that chicken egg yolk homotypic antibodies specifc for an colony-forming immunogen such as the outer membrane proteins (OMP) of Salmonella is useful as a microbial adherence inhibitor that inhibits the adhesion of *Salamonella* as an oral passive vaccine against Salmonellosis caused by Salmonella enteritidis and S. typhimurium (See abstract, (See abstract, and Materials and Methods, in particular). The recitation of drying said antibody yolk and albumin by coating the carrier material with said antibody yolk and albumin is an obvious variation of the teachings of the references.

15. Claims 14-15, 17-18, and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (Jan 1992; PTO 1449), US Pat No. 4,747,018 (May 1988; PTO 1449), Sugita-Konishi *et al* (Biosci Biotechnol Biochem 60(5): 886-8, May 1996; PTO 892) or Yokoyama *et al* (Vaccine 16(4): 388-93, Feb 1998; PTO 892) each in view of Krause *et al* (Appl Environ Microbiol 62(3): 815-21; 1996, PTO 1449) as applied to claims 1-3, 8-10, 13, 16, and 19 and further in view of US Pat 6,086,878 (Jul 2000, PTO 1449) and US Pat No. 4,166,867 (Sept 1979, PTO 1449).

The combined teachings of the '895 patent, the '018 patent, Sugita-Konishi *et al,* and Yokoyama *et al*, and Krause have been discussed supra.

The claimed invention in claim 14, 17 20 and 22 differs from the combined teachings of the references only that the microbial adherence inhibitor wherein the drying of the separated antibody-containing contents of said eggs is achieved by coating dry feed carrier material with the antibody-containing contents of said eggs.

The claimed invention in claims 15, 18, 21 and 23 differs from the combined teachings of the references only that the microbial adherence inhibitor wherein the dry feed carrier material form a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat the directly onto food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46); the reference dried egg powder can be used in drinks, protein supplement (See column 9, lines 47-8, in particular). The '878 patent further teaches there is no need to separate the yolk form the albumin, except to achieve higher concentration of antibody (See column 9, line 62-65, in particular).

The '867 patent teaches a method of making a high performance palatable horse feed comprising soybean hulls, rice hulls cottonseed hulls which provide the fibrous material and cereal grain such as corn and distilled dried grains provide the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to coat any of the animal feed such as soybean hulls, rice hulls cottonseed hulls, cereal grain such as corn and distilled dried grains as taught by the '867 patent with the microbial adherence inhibitor such as the IgY antibody that binds specifically to either *Peptostreptococcus anaerobius, Closteridium sticklandii,* or *Clostridium aminophilium* as taught by the '895 patent, the '018 patent, Sugita-Konishi *et al,* Yokoyama *et al* and Krause *et al* or IgY antibodies that bind specifically to a combination of *Peptostreptococcus anaerobius, Closteridium sticklandii,* or *Clostridium aminophilium* as taught by the '018 patent and Krause *et al* that has been spray-dried as taught by the '878 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the '867 patent teaches the carrier material such as soybean hulls, rice hulls and cottonseed hulls provide the fibrous material and provide adequate structural strength or integrity to the final feed pellets to effect stool normality (See column 3, lines 14-16, in particular). The '878 patent teaches hyperimmunized spray-dried egg powder is useful for mixing with any animal feed or sprayed directly to coat the food pellets to maintaining antibody titers (See column 9, lines 37-46). A product is a product, irrespective of its intended use.

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to "Neon" Phuong Huynh whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

18. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

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